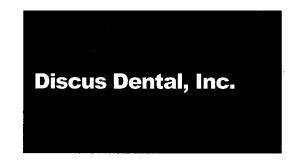
Tim Toohey
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To: USPTO From: Timothy Toohey

Fax: 571-273-8300 **Pages:** 27 (including cover)

Phone: Date: September 25, 2007

Re: Application No.: 10/056,296

Docket No.: P1083US01

Response to Final Office Action dated July 25, 2007

Dear USPTO,

Thank you,

Please find Applicant's response to the Final Office Action dated July 25, 2007.

Timothy Toohey

Assistant to Dr. Nancy Quan, Esq. Vice President and Chief IP Counsel

Customer No.: 53,096

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:

Montgomery, R.

Examiner:

Jagoe, Donna

Serial No.:

10/056,296

Group Art Unit:

1614

Filed:

January 24, 2002

Docket No.:

P1083US01

Title:

Topical Oral Care Compositions

CERTIFICATE UNDER 37 C.F.R. 1.8a:

Date of Transmission: September 25, 2007

The undersigned hereby certifies that this Transmittal Letter and the paper, as described herein and totaling 26 pages inclusively, are being transmitted to the United States Patent and Trademark Office via Facsimile under 37 CFR 1.8a to 571-273-8300.

Date: September 25, 2007

Bv:

Timothy Toohey

Mail Stop: Amendments Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

TRANSMITTAL LETTER

Dear Madam:

Enclosed herewith are the following for the above-caption application:

- 1. Transmittal Cover Letter (2 pages).
- 2. Response to Final Office Action:
 - a. Office Action Response Cover Sheet (2 page).

Customer No.: 53,096

b. Listing/Amendments to the Claims including Status Indicators (13 pages).

c. Remarks/Arguments (9 pages).

Dated: September 25, 2007

Respectfully submitted,

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:

Montgomery

Examiner:

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Serial No.:

10/056,296

Group Art Unit:

1614

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Docket No.:

P1083US01

Title:

Topical Oral Care Compositions

CERTIFICATE UNDER 37 C.F.R. 1.8a:

Date of Transmission: September 25, 2007

The undersigned hereby certifies that this Transmittal Letter and the paper, as described herein, are being transmitted to the United States Patent and Trademark Office via facsimile under 37 CTR 1.8a to 571-273-8800.

Date: September 25, 2007

By:

Timothy Toohey

Response to Final Office Action

Mail Stop Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

This paper is in response to the final office action dated July 25, 2007, setting a three month shortened statutory period for response that expires on October 25, 2007. Further examination and reconsideration of the present application in view of the remarks and arguments set forth herein are respectfully requested.

Listing / Amendments to the claims including status indicators begins on page

3

Remarks begin on page 15 of this paper.

- Claim 1. (Currently Amended): An oral care composition comprising
 - (a) an orally acceptable carrier;
- (b) an ascorbyl-2-phosphate compound having the following structure, or a sodium or potassium salt thereof,

wherein n is between 1 and 10;

- (c) a pyrophosphate, tripolyphosphate, or polyphosphate tartar control agent <u>from about 1% to about 4% by weight of the composition</u>; and
 - (d) wherein the pH of the composition is from about 5.5 to about 10.0.
- Claim 2. (Previously Presented) The composition of claim 1, wherein n is 2.
- Claim 3. (Previously Presented) The composition of claim 1, wherein n is 3.
- Claim 4. (Previously Presented) The composition of claim 1, wherein n is between 1 and 5.
- Claim 5. (Previously Presented) The composition of claim 1, further including a source of calcium ions.

Claim 6. (Canceled)

Claim 7. (Previously Presented) The composition of claim 1, wherein the ascorbyl phosphate is selected from the group consisting of ascorbyl-2-monophosphate, ascorbyl-2-diphosphate, ascorbyl-2-triphosphate, ascorbyl-2-polyphosphate, and combinations thereof.

Claim 8-10. (Canceled)

Claim 11. (Previously Presented) The composition of claim 1, wherein the tartar control agent comprises a calcium chelating agent.

Claim 12. (Previously Presented) The composition of claim 11, wherein the calcium chelating agent is selected from the group consisting of sodium pyrophosphate, potassium pyrophosphate, sodium tripolyphosphate, potassium tripolyphosphate, sodium polyphosphate, potassium polyphosphate, EDTA, a bisphosphonate, citric acid, and gluconic acid.

Claim 13. (Canceled)

Claim 14. (Canceled)

Claim 15. (Canceled)

Claim 16. (Previously Presented) The composition of claim 1, wherein the pH of the composition is about 8.86.

Claim 17. (Previously Presented) The composition of claim 1, wherein the carrier is in a dosage form selected from the group consisting of a toothpaste, gel, mouthwash, rinse, chewing gum, lozenge, floss, interdental stimulating stick, denture adhesive, buccal patch, tooth balm, dental tray-administered gel or paste, spray, chewable object, food or feed coating, topical dressing, and tooth varnish.

Claim 18. (Previously Presented) The composition of claim 1, wherein the carrier is selected from the group consisting of a water-soluble fluid, water-soluble solid, non-water soluble fluid, non-water soluble solid, humectant, thickener, surfactant, sweetener, flavorant, colorant, abrasive, stabilizer, polymeric film-forming agent, and gum base.

Claim 19. (Previously Presented) The composition of claim 18, wherein the water-soluble fluid is selected from the group consisting of water, glycerin, propylene glycol, polyethylene glycol, butylene glycol, ethyl alcohol, and mixtures thereof.

Claim 20. (Previously Presented) The composition of claim 18, wherein the water-soluble solid is selected from the group consisting of sorbitol, xylitol, maltitol, mannitol, other polyhydric alcohols, polyethylene glycol, and mixtures thereof.

Claim 21. (Previously Presented) The composition of claim 18, wherein the non-water soluble fluid is selected from the group consisting of mineral oil, vegetable oil, natural or synthetically derived fluid ester, and mixtures thereof.

- Claim 22. (Previously Presented) The composition of claim 18, wherein the non-water soluble solid is selected from the group consisting of petrolatum, wax, polybutylene, a low molecular weight waxy polymer, and mixtures thereof.
- Claim 23. (Previously Presented) The composition of claim 18, wherein the humectant is selected from the group consisting of glycerin, propylene glycol, polyethylene glycol, butylene glycol, sorbitol, xylitol, maltitol, mannitol, other polyhydric alcohol, and mixtures thereof.
- Claim 24. (Previously Presented) The composition of claim 18, wherein the thickener is selected from the group consisting of carboxypolymethylene, acrylate polymer and copolymer, carboxymethylcellulose, hydroxypropyl cellulose, hydroxyethyl cellulose, xanthan gum, poly(maleic anhydride/methyl vinyl ether), poly(vinyl pyrollidone), vinyl pyrollidone copolymers, poly(vinyl acetate), vinyl acetate copolymer, hydrated silica, fumed silica, magnesium aluminum silicate, and salts and mixtures thereof.
- Claim 25. (Previously Presented) The composition of claim 18, wherein the surfactant is selected from the group consisting of sodium lauryl sulfate, sodium lauroyl sarcosinate, sodium methyl cocoyl taurate, sodium dodecyl benzenesulfonate, sodium lauryl sulfoacetate, poloxamer, polyoxyethylene sorbitan ester, fatty alcohol ethoxylate, a polyethylene oxide condensate of alkyl phenol, cocoamidopropylbetaine, and mixtures thereof.
- Claim 26. (Previously Presented) The composition of claim 18, wherein the sweetener is selected from the group consisting of a sugar, a sugar alcohol, saccharin, potassium acesulfame, aspartame, sucralose, and mixtures thereof.

- Claim 27. (Previously Presented) The composition of claim 18, wherein the flavorant is selected from the group consisting of oil of wintergreen, oil of peppermint, oil of spearmint, methyl salicylate, menthol, thymol, anethole, oil of clove, eucalyptol, eugenol, oil of cinnamon, vanillin, and mixtures thereof.
- Claim 28. (Previously Presented) The composition of claim 18, wherein the colorant is selected from the group consisting of an orally acceptable FD&C and D&C dye, FD&C and D&C lake, zinc oxide, titanium dioxide, natural and synthetic colorant, and mixtures thereof.
- Claim 29. (Previously Presented) The composition of claim 18, wherein the abrasive is selected from the group consisting of silica, dicalcium phosphate dihydrate, dicalcium phosphate anhydrous, hydrated alumina, insoluble sodium polymetaphosphate, calcium carbonate, calcium pyrophosphate, tricalcium phosphate, and mixtures thereof.
- Claim 30. (Previously Presented) The composition of claim 18, wherein the stabilizer comprises a chelating agent selected from the group consisting of EDTA, a bisphosphonate, citric acid, and gluconic acid.
- Claim 31. (Previously Presented) The composition of claim 18, wherein the stabilizer comprises a preservative selected from the group consisting of benzoic acid and its salts, methyl
- Claim 32. (Previously Presented) The composition of claim 1, further comprising an auxiliary active ingredient selected from the group consisting of

an anticaries agent, an antiplaque agent, an antimicrobial agent, an antigingivitis agent, a desensitizing agent, and combinations thereof.

Claim 33. (Previously Presented) The composition of claim 32, wherein the anticaries agent comprises a fluoride containing compound.

Claim 34. (Previously Presented) The composition of claim 33, wherein the fluoride containing compound is selected from the group consisting of sodium fluoride, sodium monofluorophosphate, stannous fluoride, and an amine fluoride.

Claim 35. (Previously Presented) The composition of claim 32, wherein the anticaries agent comprises from about 0.1% to about 4% by weight of the composition or from about 0.2% by weight to about 0.8% by weight of the composition.

Claim 36. (Canceled)

Claim 37. (Previously Presented) The composition of claim 32, wherein the antimicrobial agent is selected from the group consisting of triclosan, chlorhexidine and its salts, cetylpyridinium chloride, and an essential oil.

Claim 38. (Previously Presented) The composition of claim 37, wherein the essential oil is selected from the group consisting of menthol, eucalyptol, thymol and methyl salicylate.

Claim 39. (Previously Presented) The composition of claim 32, wherein the antimicrobial agent comprises from about 0.01% to about 2% by weight of the composition or from about 0.1% to about 1% by weight of the composition.

Claim 40. (Canceled)

Claim 41. (Previously Presented) The composition of claim 32, wherein the desensitizing agent is selected from the group consisting of potassium nitrate, potassium citrate, and strontium chloride hexahydrate.

Claim 42. (Previously Presented) The composition of claim 32, wherein the desensitizing agent comprises from about 0.1% to about 10% by weight of the composition.

Claim 43. (Previously Presented) The composition of claim 32, wherein the desensitizing agent comprises potassium nitrate in an amount of from about 3% to about 6% by weight of the composition or in an amount of about 5% by weight of the composition.

Claim 44. (Canceled)

Claim 45. (Previously Presented) The composition of claim 1, wherein n is 1.

Claim 46. (Currently amended) <u>The</u> oral care composition <u>of claim 1</u> [comprising

(a) an orally acceptable carrier;

————]-wherein n is between 2 and 10[;

- (d) wherein the pH of the composition is from about 5.5 to about 10.0].
- 47. (Canceled) A method for reducing tooth sensitivity comprising:

 contacting a tooth surface or tooth surfaces with an oral care composition comprising
 - (a) an orally acceptable carrier; and
- (b) an ascorbyl-2-phosphate compound having the following structure, or a sodium or potassium salt thereof,

wherein n is between 1 and 10.

- 48. (Canceled) The method of claim 47 wherein the oral care composition contacts the tooth or tooth surfaces for 5 to 60 minutes.
- 49. (Canceled) The method of claim 47 further comprising contacting a tooth surface or tooth surfaces with a peroxide-containing tooth whitening composition for a period of time in order to effect tooth whitening prior to contacting with an oral care composition.
- 50. (Canceled) The method of claim 49 wherein the oral care composition contacts the tooth or tooth surfaces for 5 to 60 minutes.

51. (Canceled) A method for counteracting tooth decay or assisting in the regenerative process of periodontal tissues comprising:

contacting a tooth surfaces or tooth surfaces with an oral care composition comprising

- (a) an orally acceptable carrier; and
- (b) an ascorbyl-2-phosphate compound having the following structure, or a sodium or potassium salt thereof,

wherein n is between 1 and 10.

- 52. (Canceled) The method of claim 51 wherein the oral care composition contacts the tooth or tooth surfaces for 5 to 60 minutes.
- 53. (Canceled) A method for the prevention of tooth stain accumulation comprising:

contacting a tooth surfaces or tooth surfaces with an oral care composition comprising

(a) an orally acceptable carrier; and

(b) an ascorbyl-2-phosphate compound having the following structure, or a sodium or potassium salt thereof,

wherein n is between 1 and 10.

- 54. (Canceled) The method of claim 51 wherein the oral care composition contacts the tooth or tooth surfaces for 5 to 60 minutes.
- Claim 55. (New) An oral care composition comprising
 - (a) an orally acceptable carrier;
- (b) an ascorbyl-2-phosphate compound having the following structure, or a sodium, potassium, or calcium salt thereof,

wherein n is between 1 and 10;

- (c) a pyrophosphate, tripolyphosphate, or polyphosphate tartar control agent; and
- (d) an ingredient promoting the adherence of the composition to the tooth or tissue.
- Claim 56. (New) The composition of claim 55 further comprising an auxiliary active ingredient selected from the group consisting of an anticaries agent, an antiplaque agent, an antimicrobial agent, an antigingivitis agent, a desensitizing agent, and combinations thereof.
- Claim 57. (New) The composition of claim 55 wherein the ascorbyl phosphate is selected from the group consisting of ascorbyl-2-monophosphate, ascorbyl-2-diphosphate, ascorbyl-2-triphosphate, ascorbyl-2-polyphosphate, and combinations thereof.
- Claim 58 (New) The composition of claim 55 wherein the tartar control agent comprises a calcium chelating agent.
- Claim 59. (New) The composition of claim 58 wherein the calcium chelating agent is selected from the group consisting of sodium pyrophosphate, potassium pyrophosphate, sodium tripolyphosphate, potassium tripolyphosphate, sodium polyphosphate, potassium polyphosphate, EDTA, a bisphosphonate, citric acid, and gluconic acid.
- Claim 60. (New) The composition of claim 55 wherein said tartar control agent composition about 0.1% to about 10% by weight of the composition

Claim 61. (New) A curable composition comprising

- (a) an orally acceptable carrier;
- (b) an ascorbyl-2-phosphate compound having the following structure, or a sodium or potassium salt thereof,

wherein n is between 1 and 10; and

(c) an ingredient promoting the adherence of the composition to the tooth or tissue;

wherein said composition is cured to form a restorative or temporary cement.

- Claim 62. (New) The composition of claim 61 further comprising a pyrophosphate, tripolyphosphate, or polyphosphate tartar control agent.
- Claim 63. (New) The composition of claim 60 further comprising a source of calcium ions.

Remarks and argument

Claims 1-5, 7, 11-12, 16-35, 37-39, 41-43, 45-46, and 55-63 are pending in this application. Claims 1, 55 and 61 are independent.

Claims 1 and 46 are amended. Claim 1 is amended to incorporate part of the subject matter of claim 13. No new matter is added.

The amendment to claim 46 is not of any substantive matter. In the previous office action, Applicant erroneously used the square bracket style rather than strike through for deletions. The correct form has now been used. For this reason, Applicant respectfully submits that the amendment is purely formal in nature and no reduction in available scope of equivalents under the Doctrine of Equivalents should attach by virtue of this amendment

Claims 13, 47-54 are canceled without prejudice. Claims 47-54 have been withdrawn subject to a restriction requirement.

New claims 55-63 are added. Support for these claims is found throughout the specification and the claims originally filed. No new matter is added.

Reconsideration is respectfully requested.

I. Rejection under 35 U.S.C. 103(a)

1. Claims 1-5, 7, 11-13, 16-35, 37-39, 41-43 and 45-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Show Denko KK JP 62096408 in view of Pera U.S. Patent No. 4,775,525. and Elliott et al. U.S. Patent No. 5,011,682.

The claims are drawn to a composition comprising ascorbyl-2-phosphate or a sodium or potassium salt thereof and further comprising calcium ions wherein the composition is mixed with an orally acceptable carrier, and further comprising a calcium chelating agent, a pyrophosphate, tripolyphosphate or

polyphosphate tartar control agent, a water soluble fluid, water soluble solid, humectant, thickener, surfactant, sweetener, flavorant, colorant, abrasive, stabilizer, fluoride containing compound, anticaries agent, antimicrobial agent, essential oil and a desensitizing agent.

Showa Denko KK teach ascorbic acid phosphoric acid ester or it's salt (e.g. Na⁺, K⁺ Ca⁺⁺ or Mg⁺ salt) in an oral composition to be used for alveolar pyorrhea, cleaning teeth, removing bad breath and washing the teeth. It is in compositions such as toothpaste, chewing gum and troches. Working example I teaches calcium diphosphate dihydrate (source of calcium/abrasive), sodium carboxymethylcellulose and carrageenan (thickeners), glycerin (water soluble liquid), sorbital (water soluble solid), fragrance (flavor), preservative (antimicrobial), sodium saccharin (sweetener), sodium lauryl sulfate (surfactant), and ascorbic acid magnesium phosphate.

Showa Denko does not teach the desensitizing agents of claims 40-44, it does not teach the non water-soluble solid and liquid and it does not teach the pyrophosphate, tripolyphosphate or polyphosphate tartar control agent.

Pera (4,775,525) teaches strontium as a desensitizing agent for the teeth (column 5, lines 27-43).

It would have been made obvious to one of ordinary skill in art at the time it was made to incorporate desensitizing agents and vegetable oils and wax. Such a modification would have been motivated by the reasoned expectation of producing a dentifrice composition which is effective in comprehensively cleaning teeth and desensitizing teeth of individuals that have become sensitized. Strontium is a well known desensitizer, which is known and used in dentifrices as evidenced by the teachings of Pera (4,775,525). Vegetable oil would aid in mixing the dentifrice composition and the wax would effectively coat the teeth and add shine to the teeth.

Elliott et al. teach Soluble inorganic pyrophosphate salts have over the last few years set the commercial standard as tartar control agents (column 1, lines 26-31) and teach tartar control agents such as disodium pyrophosphate, dipotassium pyrophosphate, tetrapotassium pyrophosphate, tetrasodium pyrophosphate to a dentifrice composition (column 5, lines 5-16).

It would have been made obvious to one of ordinary skill in art at the time it was made to incorporate the instantly recited tartar control agents. Such a modification would have been motivated by the reasoned expectation of producing a dentifrice composition, which is effective in comprehensively cleaning teeth and removing tartar. As stated in Elliott, the pyrophosphate tartar control agents have set the commercial standard and are known and used in dentifrices as evidenced by the teachings of Elliott et al.

Applicant claims a pH of the composition from about 5.5 to about 10.0 now in independent claim 1. However, if applicant wishes to rely on provisional application number 60/263884 ,for a priority date of 1/24/01, the only pH present in the priority document is a teaching of a pH of 8.86 in one specific formulation. There is no recitation of a pH of from about 5.5 to about 10.

See http://pubs.acs.org/hotartcl/chemtech/95/dec/dec.html December 1995 wherein it is recited that Sodium fluoride, sodium monofluorophosphate, and stannous fluoride are the most common fluoride sources used in toothpaste. Great care must be taken in the formulation of these agents so that their anticaries activity is not reduced by other dentifrice ingredients, such as the abrasive system. For example, whereas sodium monofluorophosphate is compatible with both silica and dicalcium phosphate dihydrate abrasives, sodium fluoride is most compatible with the silica abrasive at neutral pH values. Thus it would have been obvious to employ a pH of 5.5 to 10 since this range

encompasses neutral pH's and this would be most compatible for formulations with fluoride.

Applicant respectfully traverses the rejection.

Showa Denko KK teach ascorbic acid phosphoric acid ester or it's salt (e.g. Na⁺, K⁺ Ca⁺⁺ or Mg⁺ salt) in an oral composition to be used for alveolar pyorrhea, cleaning teeth, removing bad breath and washing the teeth. It is in compositions such as toothpaste, chewing gum and troches. However, since calcium diphosphate dehydrate is taught as an abrasive, large amounts of the material is used, specifically 45%. There is no teaching of a tartar control agent in the amounts of about 1 to about 4% of the composition in combination with an ascorbyl-2-phosphate compound, or a sodium or potassium salt thereof, at a pH of about 5.5 to about 10. See amended claim 1 of the present invention.

Pera U.S. Patent No. 4,775,525 discloses "providing an ingestible toothpaste which when used on a daily basis, is primarily intended to remove dental plaque and secondarily intended to reduce hypersensitivity, and halitosis." See Col. 3, lines 42-46, emphasis added. "The essential active ingredient of the present invention is a calcium ion chelating agent comprising sodium alginate. The removal of calcium ions weakens plaque so that it may be easily removed by brushing or other mild forms of abrading actions." See Col. 3, lines 51-55. Thus, Pera essentially teaches the use of sodium alginate as a plaque removal agent in an ingestible toothpaste and teach away from the use of normal tartar control agents and abrasives. "In general, while no abrasive is harsh enough to remove enamel, some dentifrices may harm cementum and dentin. These products should be avoided by individuals with periodontal disease and hypersensitive teeth. Identifying the different kinds of offending dentifrices is difficult because the interaction of inert ingredients in each formula (which changes over time) may enhance or retard the effect of the abrasive within the

mixture. In general, powders are more abrasive than pastes, and products that claim to be tooth whiteners often are harsher than others. Specific abrasive ingredients which may harm dentin include calcium carbonate, anhydrous dibasic calcium phosphate and silica." See Col. 1, line 57 to Col. 2, line 3. (Emphasis added).

Elliott et al. U.S. Patent No. 5,011,682 discloses yet another anti-tartar agent having "a random polymeric residue comprising at least one unit of structure II". See Col. 2, lines 22-45. "When in the form of a toothpaste or gel, the oral compositions will normally include an abrasive. Abrasives may be selected from water-insoluble alkali or alkaline earth metal salts of metaphosphate, calcium carbonate, aluminates and silicates. Especially preferred are silicate, dicalcium phosphate and calcium carbonate. Amounts of the abrasive will range from about 5% to about 80% by weight." See Co. 4, line 65 to Col. 5, line 4. (Emphasis added). "Adjunct tartar control agents, especially those containing phosphorous, may be combined with the polymers of the present invention. Inorganic phosphorous adjuncts may include any of the water-soluble pyrophosphates such as disodium pyrophosphate, dipotassium pyrophosphate and mixtures of these with tetrapotassium pyrophosphates or tetrasodium pyrophosphates. Organic phosphorous compounds that may serve as adjuncts include polyphosphonates such as disodium ethane-1-hydroxy-1, 1diphosphonate (EHDP), methanediphosphonic acid, and 2-phosphonobutane-1,2,4-tricarboxylic acid." See Col. 5, lines 5-25. Thus, while Elliott et al. discloses that "soluble inorganic pyrophosphate salts have over the last few years set the commercial standard as tartar control agents" (column 1, lines 26-31) and that "tartar control agents such as disodium pyrophosphate, dipotassium pyrophosphate, tetrapotassium pyrophosphate, tetrasodium pyrophosphate" may be added to a dentifrice composition" (column 5, lines 5-16), Elliott

essentially teaches away from such tartar control materials, except for use as abrasive agents, in favor of "a random polymeric residue comprising at least one unit of structure II".

Therefore, neither Pera nor Elliott or both supplies the deficiencies of Showa Denko KK, and actually teaches away from the present invention.

The article of http://pubs.acs.org/hotartcl/chemtech/95/dec/dec.html

December 1995 cited by the Examiner may teach what the Examiner notes, i.e.,

"wherein it is recited that Sodium fluoride, sodium monofluorophosphate, and
stannous fluoride are the most common fluoride sources used in toothpaste.

Great care must be taken in the formulation of these agents so that their
anticaries activity is not reduced by other dentifrice ingredients, such as the
abrasive system. For example, whereas sodium monofluorophosphate is
compatible with both silica and dicalcium phosphate dihydrate abrasives,
sodium fluoride is most compatible with the silica abrasive at neutral pH
values". However, this reference also teaches away from the instant invention
because knowing that a neutral pH is desired does not supply the deficiencies of
Show Denko KK JP 62096408 in view of Pera U.S. Patent No. 4,775,525 and Elliott
et al. U.S. Patent No. 5,011,682.

Additionally, Applicant respectfully submits that the Examiner's reasoning is hind sight reconstruction, using Applicant's invention as a template. Absent Applicant's invention, there is no teaching of how to pick and choose bits and pieces from the prior art. Even if such bits and pieces are chosen, there will still be no invention without adding insight from Applicant's teaching.

Applicant respectfully requests that the rejection of claims 1-5, 7, 11-13, 16-35, 37-39, 41-43 and 45-46 under 35 U.S.C. 103(a) as being unpatentable over Show Denko KK JP 62096408 in view of Pera U.S. Patent No. 4,775,525. and

Elliott et al. U.S. Patent No. 5,011,682 be withdrawn. Reconsideration is respectfully requested.

As for the Examiner note that if applicant wishes to rely on provisional application number 60/263884, for a priority date of 1/24/01, the only pH present in the priority document is a teaching of a pH of 8.86 in one specific formulation and that there is no recitation of a pH of from about 5.5 to about 10, Applicant respectfully submits that Applicant's claim of a pH of the composition from about 5.5 to about 10.0 now in independent claim 1 is fully supported by the provisional application. In the provisional application, the compositions listed on page 3, cover a large range of compositions whose pH is in the range of about 5.5 to about 10. For example, sodium ascorbyl phosphate has a pH of 9-10 at a 3% solution. See http://www.sciencelab.com/page/S/PVAR/10426/SLS3580. A 0.4 M solution (1.68%) of sodium fluoride (molecular weight of 42) has a pH 3 to 4. See http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=243760. Based on these known values, it can be seen that the pH range is about 5.5 to about 10. Reconsideration is respectfully requested.

II. New Claim Rejections -35 USC § 112

Claims 13, 35, 39, 43 and 46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant respectfully traverses the rejection.

Claims 13, 35, 39 and 43 are presented in what Applicant believes to be a correct Markush format, comprising one range of values or another range of values. Reconsideration is respectfully requested.

In addition, Applicant has canceled claim 13. Its rejection is therefore mooted.

As for claim 46, Applicant has now corrected the clerical error, using strike through for deletions. Favorable action is respectfully requested.

III. Restriction Requirement

The Examiner notes that claims 47-54 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the claims are directed to a method for reducing tooth sensitivity, counteracting tooth decay or assisting in the regenerative process of periodontal tissues and a method for the prevention of tooth stain accumulation.

Accordingly, claims 47-54 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Applicant has confirmed such restriction and the claims are now canceled from the present application. Applicant reserves the right to file the claims directed to a non-elected invention in a divisional.

IV. New Claims

New claims 55-63 are added. Claims 55 and 61 are independent. A corresponding number of claims are canceled.

Claim 55 is similar in scope to originally submitted claim 9. No new matter is added.

Claim 61 is fully supported throughout the specification, specifically, for example, by the disclosure, for example, on page 10, lines 5-10. No new matter is added.

Applicant believes that these new claims are patentable over the references cited by the Examiner. There is no teaching in the cited art of the subject matter of claims 55 and 61. Favorable action is respectfully requested.

CONCLUSION

In view of the remarks provided above, it is believed that all pending claims are in condition for allowance. Applicants respectfully request favorable reconsideration and early allowance of all pending claims: 1-5, 7, 11-13, 16-35, 37-39, 41-43, 45-46, and new claims 55-63.

If a telephone conference would be helpful in resolving any issues concerning this communication, please contact the undersigned at 310-845-8501.

Dated: Sapt 25, 200)

Respectfully submitted,

Nancy N. Quan

Reg. 36, 248

BriteSmile Professional, LLC,

8550 Higuera Street

Culver City, California 90232

Direct Line: 310-845-8501

Facsimile: 310-845-8619

NancyQ@DiscusDental.com

TRANSMISSION VERIFICATION REPORT

TIME NAME 09/25/2007 18:27

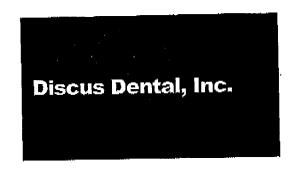
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DATE,TIME FAX NO./NAME DURATION PAGE(S) RESULT MODE 09/25 18:22 915712738300 00:05:50 27 OK STANDARD

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To: USPTO From: Timothy Toohey

Fax: 571-273-8300 Pages: 27 (including cover)

Phone: Date: September 25, 2007

Re: Application No.: 10/056,296
Docket No.: P1083US01
Response to Final Office Action dated July 25, 2007

Dear USPTO,

Please find Applicant's response to the Final Office Action dated July 25, 2007.

